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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/700,165	11/09/2000	Robert Denham Pinnock	5771-01-EMA	2583

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EXAMINER

DELACROIX MUIRHEI, CYBILLE

ART UNIT	PAPER NUMBER
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1614

DATE MAILED: 08/12/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/700,165

Applicant(s)

PINNOCK ET AL.

Examiner

Cybille Delacroix-Muirheid

Art Unit

1614

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on Dec. 4, 2002 and May 21, 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-42 is/are pending in the application.
- 4a) Of the above claim(s) 5-11, 14-16, 22-26, 28, 29 and 31-42 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1, 2, 12, 13, 17-19, 27 and 30 is/are rejected.
- 7) ☒ Claim(s) 3, 4, 20 and 21 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 09 November 2000 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>2, 5, 6</u> . | 6) <input type="checkbox"/> Other: _____ |

Detailed Action

The following is responsive to Applicant's election received Dec. 4, 2002 and the interview summary of May 21, 2003.

Response to Applicant's Election

Applicant's election of sexual dysfunction and the compound described in claims 17 and 30, with traverse, is acknowledged. However, since Applicant has not pointed out the alleged errors in the election requirement, it is maintained for reasons already of record.

No prior art was found using Applicant's elected compound used in a method for treating or preventing sexual dysfunction. Therefore, the Examiner expanded the search for the use of the elected compound in treating one of the non-elected disorders.

Claims 5-11, 14-16, 22-26, 28, 29 are withdrawn from consideration.

Information Disclosure Statement(s)

Applicant's Information Disclosure Statements received Sep. 3, 2002, Aug. 8, 2002 and April 9, 2001 have been considered. Please refer to Applicant's copies of the 1449's submitted herewith.

Abstract

Applicant is reminded of the proper language and format for an abstract of the disclosure.

The abstract should be in narrative form and generally limited to a ***single paragraph*** on a separate sheet within the range of 50 to 150 words. It is important that the abstract not exceed 150 words in length since the space provided for the abstract on the computer tape used by the printer is limited. The form and legal phraseology

Art Unit: 1614

often used in patent claims, such as "means" and "said," should be avoided. The abstract should describe the disclosure sufficiently to assist readers in deciding whether there is a need for consulting the full patent text for details.

The language should be clear and concise and should not repeat information given in the title. It should avoid using phrases which can be implied, such as, "The disclosure concerns," "The disclosure defined by this invention," "The disclosure describes," etc.

Applicant's abstract is not limited to a single paragraph. Appropriate correction is respectfully requested.

Claim Objection(s)

1. Claims 1 and 18 are objected to because of the following informalities: in claim 1, page 30, line 4, before "pyridyl", the "and" should be cancelled and replaced with --or--. In claim 18, page 33, line 8, before "pyridyl", the term "and" should be cancelled and replaced with --or--. Appropriate correction is required.

Claim Rejection(s)—35 USC 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

Art Unit: 1614

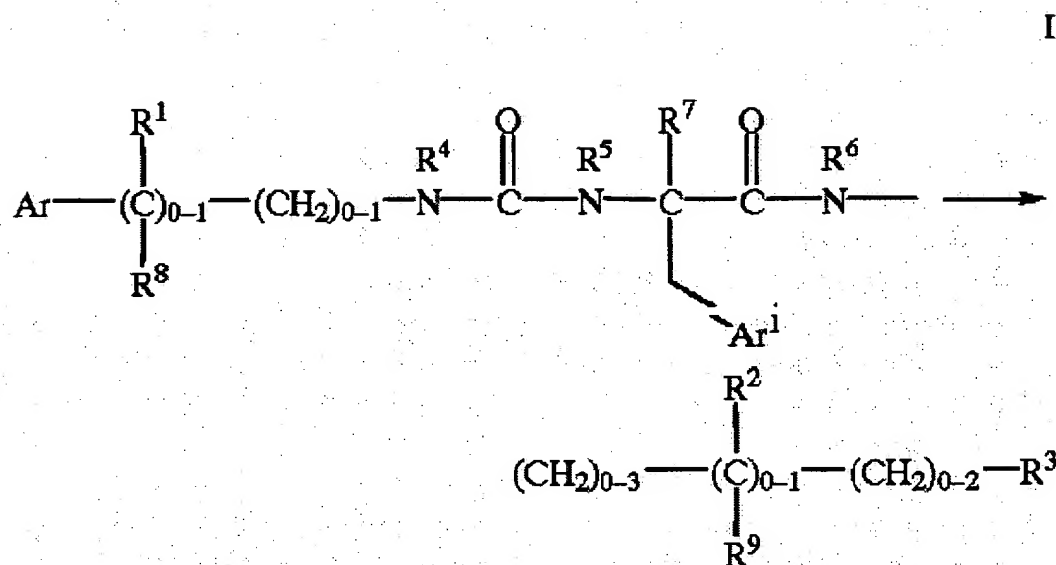
1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

2. Claims 1, 2, 12, 13, 17, 18, 19, 27, 30 are rejected under 35 U.S.C. 103(a) as being unpatentable over Horwell et al., 6,194,437 B1.

Horwell et al. disclose methods for treating and/or preventing disorders such as gastrointestinal disorders, i.e. colitis, Crohn's disease and inflammatory bowel disease by administering to a patient in need thereof an effective amount of the compound of Formula I

Art Unit: 1614



or a pharmaceutically acceptable salt thereof wherein

the substituents are defined at col. 2, lines 15-64. Please also see the abstract; col. 1, lines 55-63.

Horwell et al. do not specifically disclose administering Applicant's claimed species (claims 17, 30). However, it would have been obvious to one of ordinary skill in the art at the time the invention was made to select any of the species of the genus taught by Horwell et al., including the species of claims 17 and 30, because one of ordinary skill in the art would reasonably expect that any of the species of the genus would have similar properties and thus the same use as the genus as a whole. Moreover, it has been held that a prior art disclosed genus of useful compounds is sufficient to render prima facie obvious a species falling within the genus. Please see In

re Susi, 169 USPQ 423, 425 (CCPA 1971), followed by the Federal Circuit in Merck & Co. v. Biocraft Laboratories, 10 USPQ2d 1843, 1846 (Fed. Cir. 1989).

Claims 3-4 and 20-21 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

3. Claims 1, 2, 12, 13, 17, 18, 19, 27, 30 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1, 15 of U.S. Patent No. 6,194,437. Although the conflicting claims are not identical, they are not patentably distinct from each other because both the instant application and USPN '437 claim a method for treating gastrointestinal disorders by administering effective amounts of the compound represented by Formula (I), wherein the difference between the claims of the instant application and the claims of USPN '437 is that USPN '437

does not claim a method of treating gastrointestinal disorders by administering an effective amount of the species claimed by the instant application (see claims 17 and 30).

However, it would have been obvious to one of ordinary skill in the art at the time the invention was made to select any of the species of the genus claimed by USPN '437, including the claimed species of the instant application, because one of ordinary skill in the art would reasonably expect that any of the species of the genus would have similar properties and thus the same use as the genus as a whole, i.e. the species would be capable of treating gastrointestinal disorders.

Conclusion

Claims 1, 2, 12, 13, 17, 18, 19, 27, 30 are rejected.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Cybille Delacroix-Muirheid whose telephone number is 571-272-0572. The examiner can normally be reached on Mon-Thurs. and every other Friday from 8:30 to 6:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christopher Low, can be reached on 571-272-0951. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only.

Art Unit: 1614

For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic

Business Center (EBC) at 866-217-9197 (toll-free).

CDM

August 8, 2004


Cybille Delacroix-Muirheid
Patent Examiner Group 1600